

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

THIS DOCUMENT RELATES TO:
State of Iowa v. Abbott Laboratories, et al.

MDL No. 1456
Master File No.: 01-CV-12257-PBS
(original S. D. Iowa No. 4:07-cv-00461-
JAJ-CFB)

Judge Patti B. Saris

**ANSWER AND AFFIRMATIVE DEFENSES OF SANDOZ INC.
TO THE STATE OF IOWA'S COMPLAINT**

Defendant Sandoz Inc. ("Sandoz"), by and through its attorneys, hereby states as an Answer and Affirmative Defenses to the State of Iowa's Complaint, dated October 9, 2007, as follows. Unless expressly admitted, Sandoz denies each and every allegation in the Complaint, and all allegations containing legal arguments and/or conclusions of law on the ground that such allegations do not require a response. Sandoz also denies any allegations set forth in the table of contents and headings to the Complaint.

The State of Iowa's Complaint (the "Complaint") improperly refers to Sandoz, other Defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against Sandoz. This is insufficient to apprise Sandoz of the allegations asserted against it. Sandoz has nevertheless attempted to respond to Plaintiff's allegations to the extent possible.

SPECIFIC RESPONSES

1. Sandoz denies the allegations contained in paragraph 1 insofar as they pertain to Sandoz, except admits that the State of Iowa (the "State") purports to bring

claims on behalf of its Medicaid program and certain of its citizens. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 1 and therefore denies them.

2. Sandoz denies the allegations contained in paragraph 2 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 2 and therefore denies them.

3-4. Sandoz denies the allegations contained in paragraphs 3-4 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 3-4 and therefore denies them.

5. Sandoz denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 and therefore denies them.

6. Sandoz denies the allegations contained in Paragraph 6 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 6 and therefore denies them.

7. Sandoz denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 7 and therefore denies them.

8. Sandoz denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 8 and therefore denies them.

9. Sandoz denies the allegations contained in paragraph 9 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 9 and therefore denies them.

10. Sandoz denies the allegations contained in paragraph 10 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10 and therefore denies them.

11. Sandoz denies the allegations contained in paragraph 11 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11 and therefore denies them.

12. Sandoz denies the allegations contained in paragraph 12 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12 and therefore denies them.

13. Sandoz denies the allegations contained in paragraph 13 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13 and therefore denies them.

14. Sandoz denies the allegations contained in paragraph 14 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 14 and therefore denies them.

15. Sandoz denies the allegations contained in paragraph 15 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 15 and therefore denies them.

16. Sandoz denies the allegations contained in paragraph 16 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 16 and therefore denies them.

17. Sandoz denies the allegations contained in paragraph 17 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 17 and therefore denies them.

18. Sandoz denies the allegations contained in paragraph 18 and Exhibit B-1 through B-33 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 18 and Exhibit B-1 through B-33 and therefore denies them.

19. Sandoz denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 and therefore denies them.

20. Sandoz denies the allegations contained in paragraph 20 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 20 and therefore denies them.

21. Sandoz denies the allegations contained in paragraph 21 insofar as they pertain to Sandoz, except admits that it sells drugs in Iowa. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 20 and therefore denies them.

22-44. Sandoz responds that the allegations contained in paragraphs 22-44 are directed to other Defendants and do not require an answer from Sandoz. To the extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 24-44 and therefore denies them.

45. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 45(a), except admits that the principal place of business of Novartis Pharmaceuticals Corporation is East Hanover, New Jersey. Sandoz further admits that its principal place of business is 506 Carnegie Center, Suite 400, Princeton, NJ 08540-6243, and that it develops, manufactures, and sells generic pharmaceuticals. Sandoz also states that it is a Colorado corporation, and that the company, misidentified in the Complaint as “Sandoz, Inc.,” was

formerly known as “Geneva Pharmaceuticals, Inc.” Sandoz denies the remaining allegations of paragraph 45.

46-58. Sandoz responds that the allegations contained in paragraphs 46-58 are directed to other Defendants and do not require an answer from Sandoz. To the extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 46-58 and therefore denies them.

59. Paragraph 59 contains legal conclusions as to which no answer is required. To the extent that an answer may be required, Sandoz denies the allegations of paragraph 39 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 59 and therefore denies them.

60. Paragraph 60 contains legal conclusions as to which no answer is required. To the extent that an answer may be required, Sandoz denies the allegations of paragraph 60 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 60 and therefore denies them.

61. Paragraph 61 contains legal conclusions as to which no answer is required. To the extent that an answer may be required, Sandoz denies the allegations of paragraph 61 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 61 and therefore denies them.

62. Paragraph 62 contains legal conclusions as to which no answer is required. To the extent that an answer may be required, Sandoz denies the allegations of paragraph 62 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 62 and therefore denies them.

63. Paragraph 63 contains legal conclusions as to which no answer is required. To the extent that an answer may be required, Sandoz denies the allegations of paragraph 63 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 63 and therefore denies them.

64. Paragraph 64 contains legal conclusions as to which no answer is required. To the extent that an answer may be required, Sandoz denies the allegations of paragraph 64 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 64 and therefore denies them.

65. Paragraph 65 contains legal conclusions as to which no answer is required. To the extent that an answer may be required, Sandoz denies the allegations of paragraph 65 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 65 and therefore denies them.

66. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 66 and therefore denies them.

67. Paragraph 67 contains legal conclusions as to which no answer is required. To the extent that an answer may be required, Sandoz denies the allegations of paragraph 67 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 67 and therefore denies them.

68. Sandoz denies knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68. To the extent the allegations in Paragraph 68 refer to an OIG report, the report speaks for itself, and any characterizations thereof are denied.

69. Sandoz denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 69 and therefore denies them.

70. Sandoz denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70 and therefore denies them.

71-73. Sandoz denies the allegations of paragraphs 71-72 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 71-72 and therefore denies them.

74-79. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 74-79 and therefore denies them.

80. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 74-79 and therefore denies them. Sandoz denies the allegations contained in Exhibit B insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Exhibit B and therefore denies them.

81. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 112 and therefore denies them, except admits that pricing compendia such as First DataBank and Medi-Span publish AWP's and FUL's, and denies that Sandoz has any control over such prices.

82. Sandoz denies the allegations contained in paragraph 82 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 82 and therefore denies them.

83. Sandoz denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 83 and therefore denies them.

84. Sandoz denies the allegations contained in paragraph 84 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 84 and therefore denies them.

85. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 85 and therefore

denies them. Sandoz denies the allegations contained in Exhibit A insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Exhibit A and therefore denies them.

86. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 86 and therefore denies them.

87-100. Sandoz denies the allegations contained in paragraphs 87-100 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 87-100 and therefore denies them.

101. Sandoz denies the allegations contained in paragraph 100 and Exhibit C insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 100 and Exhibit C and therefore denies them.

102-107. Sandoz denies the allegations contained in paragraphs 100-107 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 102-107 and therefore denies them.

108. Sandoz denies the allegations contained in paragraph 108 and Exhibit B insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or

information sufficient to form a belief as to the truth of the remaining allegations of paragraph 108 and Exhibit B and therefore denies them.

109. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 109 and therefore denies them.

110-132. Sandoz responds that the allegations contained in paragraphs 110-132 are directed to another Defendant and do not require an answer from Sandoz, and further states that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to Sandoz.. To the extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 110-132 and therefore denies them.

133-141. Sandoz denies the allegations contained in paragraphs 133-141 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of remaining allegations of paragraphs 133-141 and therefore denies them.

142. Sandoz responds that the allegations contained in paragraph 142 are directed to another Defendant and do not require an answer from Sandoz. To the extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 142 and therefore denies them.

143. Sandoz denies the allegations contained in paragraph 143 and Exhibit B insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or

information sufficient to form a belief as to the truth of remaining allegations of paragraph 143 and Exhibit B and therefore denies them.

144-145. Sandoz denies the allegations contained in paragraphs 144-145 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of remaining allegations of paragraphs 144-145 and therefore denies them.

146-150. Sandoz denies the allegations contained in paragraphs 146-150 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 146-150 and therefore denies them.

151. Sandoz responds that the allegations contained in paragraph 151 are directed to other Defendants and do not require an answer from Sandoz. To the extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 151 and therefore denies them.

153-154. Sandoz denies the allegations contained in paragraphs 153-154 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 153-154 and therefore denies them.

155-158. Sandoz denies the allegations contained in paragraphs 155-158 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information

sufficient to form a belief as to the truth of the remaining allegations of paragraphs 155-158 and therefore denies them.

159-166. Sandoz denies the allegations contained in paragraphs 159-166 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 159-166 and therefore denies them.

167-171. Sandoz denies the allegations contained in paragraphs 167-171 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 167-171 and therefore denies them.

172-177. Sandoz denies the allegations contained in paragraphs 172-177 and Exhibit B insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 172-177 and Exhibit B and therefore denies them.

178-180. Sandoz denies the allegations contained in paragraphs 178-180 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 178-180 and therefore denies them.

181-473. Sandoz responds that the allegations contained in paragraphs 181-473 are directed to another Defendant and do not require an answer from Sandoz. To the extent an answer may be required, Sandoz states that it is without knowledge or

information sufficient to form a belief as to the truth of the allegations of paragraphs 181-473 and therefore denies them.

474. Sandoz denies the allegations contained in paragraph 474 and Exhibit A insofar as they pertain to Sandoz, except states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 474 and Exhibit A and therefore denies them. Sandoz specifically denies the existence of a “Novartis/Sandoz Group.”

475. Sandoz denies the allegations contained in paragraph 475 and Exhibit B insofar as they pertain to Sandoz. Sandoz specifically denies the existence of a “Novartis/Sandoz Group.” Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 475 and Exhibit B and therefore denies them.

476. Sandoz denies the allegations contained in paragraph 476 insofar as they pertain to Sandoz. Sandoz specifically denies the existence of a “Novartis/Sandoz Group.” Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 476 and therefore denies them.

477. Sandoz responds that the allegations contained in paragraph 477 are directed to another Defendant and do not require an answer from Sandoz. To the extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 477 and therefore denies them.

478. Sandoz denies the allegations contained in paragraph 478 insofar as they pertain to Sandoz. Sandoz specifically denies the existence of a “Novartis/Sandoz Group.” Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 478 and therefore denies them.

479. Sandoz denies that it has engaged in wrongful conduct and otherwise responds that the allegations contained in paragraph 479 are directed to another Defendant and do not require an answer from Sandoz. To the extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 479 and therefore denies them.

480. Sandoz responds that the allegations contained in paragraph 480 are directed to another Defendant and do not require an answer from Sandoz. To the extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 480 and therefore denies them.

481. Sandoz denies the allegations contained in paragraph 481 insofar as they pertain to Sandoz, except admits that it received a June 26, 2003 letter from Representatives Tauzin and Greenwood, and refers to the letter for its terms. Sandoz responds that the remainder of the allegations of paragraph 481 are directed to another Defendant and do not require an answer from Sandoz.

482-613. Sandoz responds that the allegations contained in paragraphs 482-613 are directed to another Defendant and do not require an answer from Sandoz. To the

extent an answer may be required, Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraphs 482-613 and therefore denies them.

614-616. Sandoz denies the allegations contained in paragraphs 614-616 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 614-616 and therefore denies them.

617-629. Sandoz denies the allegations contained in paragraphs 617-629 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 617-629 and therefore denies them.

634-642. To the extent the allegations in paragraphs 634-642 are directed at Sandoz, Sandoz states that the Court has dismissed Count I by Order dated August 19, 2008 and, therefore, no answer is required.

643-651. To the extent the allegations in paragraphs 643-651 are directed at Sandoz, Sandoz states that the Court has dismissed Count II as to Sandoz by Order dated August 19, 2008 and, therefore, no answer is required.

652. Sandoz incorporates by reference its answers to paragraphs 1-651 above.

653-657. Sandoz denies the allegations contained in paragraphs 653-657 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information

sufficient to form a belief as to the truth of the remaining allegations of paragraphs 653-657 and therefore denies them.

658. Sandoz incorporates by reference its answers to paragraphs 1-657 above.

659-662. Sandoz denies the allegations contained in paragraphs 659-662 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 659-662 and therefore denies them.

663. In response to Paragraph 663, Sandoz repeats and incorporates as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 662.

664-666. Sandoz denies the allegations contained in paragraphs 664-666 insofar as they pertain to Sandoz. Sandoz states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraphs 664-666 and therefore denies them.

PRAYER FOR RELIEF

667-675. Sandoz further denies any allegations in paragraphs 667-675 and denies that Plaintiff is entitled to any relief.

WHEREFORE, Sandoz demands judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

AFFIRMATIVE DEFENSES

By making the assertions set forth below, Sandoz does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these assertions or that Plaintiff is relieved of its burdens to prove each and every element of its claims and the damages, if any, to which it is entitled. As and for its affirmative defenses, Sandoz states as follows:

FIRST AFFIRMATIVE DEFENSE

1. Plaintiff fails to state a claim against Sandoz upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

2. The State's unjust enrichment claims are barred, in whole or in part, because the State has no authority to bring such claims either on behalf of itself or on behalf of Medicare Part B participants.

THIRD AFFIRMATIVE DEFENSE

3. Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit to recover Medicaid or Medicare expenditures or to seek injunctive relief related to either of these programs.

FOURTH AFFIRMATIVE DEFENSE

4. Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Sandoz as alleged in the Complaint.

FIFTH AFFIRMATIVE DEFENSE

5. To the extent Plaintiff obtains recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against Sandoz based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

SIXTH AFFIRMATIVE DEFENSE

6. Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Iowa.

SEVENTH AFFIRMATIVE DEFENSE

7. Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

EIGHTH AFFIRMATIVE DEFENSE

8. Any and all actions taken by Sandoz with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice

NINTH AFFIRMATIVE DEFENSE

9. Plaintiff's claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated there under.

TENTH AFFIRMATIVE DEFENSE

10. Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

ELEVENTH AFFIRMATIVE DEFENSE

11. Plaintiff's claims against Sandoz are barred because Sandoz has complied with all applicable regulations of the federal government, the State of Iowa and other state governments.

TWELFTH AFFIRMATIVE DEFENSE

12. Plaintiff's claims against Sandoz are barred, in whole or in part, by the applicable statute of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

THIRTEENTH AFFIRMATIVE DEFENSE

13. Plaintiff's claims are barred, in whole or in part, because they violate Sandoz's rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as the Constitution of the State of Iowa, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

FOURTEENTH AFFIRMATIVE DEFENSE

14. Sandoz's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff.

FIFTEENTH AFFIRMATIVE DEFENSE

15. To the extent that Plaintiff attempts to seek equitable relief against Sandoz, it is not entitled to such relief because it has an adequate remedy at law.

SIXTEENTH AFFIRMATIVE DEFENSE

16. Plaintiff's claims against Sandoz for injunctive relief were mooted, at least in part, by the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

SEVENTEENTH AFFIRMATIVE DEFENSE

17. Plaintiff's claims for injunctive relief against Sandoz are barred by the doctrines of in pari delicto and/or unclean hands.

EIGHTEENTH AFFIRMATIVE DEFENSE

18. Plaintiff's claims against Sandoz are barred, in whole or in part, due to its failure to join indispensable parties.

NINETEENTH AFFIRMATIVE DEFENSE

19. Plaintiff's claims against Sandoz are barred, in whole or in part, because it has suffered no damages as a result of the matters alleged in the Complaint.

TWENTIETH AFFIRMATIVE DEFENSE

20. Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of non parties.

TWENTY-FIRST AFFIRMATIVE DEFENSE

21. Plaintiff's claims against Sandoz for damages are barred, in whole or in part:

(1) because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery of Plaintiff and the allocation of any fault, if any exists, attributable to Sandoz;

(2) because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint;

(3) by the doctrine of consent and/or ratification to the extent that Plaintiff has paid for products manufactured, marketed and sold by Sandoz after the filing of Plaintiff's original Complaint; and

(4) because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.

TWENTY-SECOND AFFIRMATIVE DEFENSE

22. Sandoz is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

TWENTY-THIRD AFFIRMATIVE DEFENSE

23. Any damages recovered by Plaintiff from Sandoz must be limited by the applicable statutory ceilings on recoverable damages.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

24. Plaintiff fails to allege facts or a cause of action against Sandoz sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, or any other relief.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

25. To the extent penalty assessments are sought, Plaintiff's penalty assessments claims against Sandoz:

(1) have no basis in law or fact;

(2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for penalty assessments against Sandoz;

(3) cannot be sustained because the laws regarding the standards for determining liability for and the amount of penalty assessments fail to give Sandoz prior notice of the conduct for which penalty assessments may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Sandoz's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Iowa;

(4) cannot be sustained because any award of penalty assessments exceeding the limits authorized by the laws or other comparable laws would violate Sandoz's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and laws of the State of Iowa;

(5) cannot be sustained because an award of penalty assessments in this case, combined with any prior, contemporaneous, or subsequent judgments against Sandoz for penalty assessments arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Sandoz's products would constitute impermissible multiple punishments for the same wrong, in violation of Sandoz's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law, and statutory laws of the State of Iowa;

(6) cannot be sustained because any award of penalty assessments without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Sandoz's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Iowa; and

(7) cannot be sustained because any award of penalty assessments, which are penal in nature, without according Sandoz the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Sandoz's rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Iowa.

(8) cannot be sustained because it is impermissible to impose penalty assessments, which are penal in nature, upon civil defendant upon the State satisfying a burden of proof less than the "beyond a reasonable doubt" burden of proof required in criminal cases, and to do so would violate Sandoz's rights guaranteed by the Fourth, Fifth, and Sixth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Iowa.

(9) cannot be sustained because the procedures pursuant to which any penalty assessments would be awarded permit the imposition of an excessive fine and would violate Sandoz's rights under the Eighth Amendment as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of Iowa.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

26. To the extent penalty assessments are sought, Plaintiff's claims for penalty assessments against Sandoz cannot be sustained because an award of penalty assessments by a jury that:

(1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a penalty assessments award;

(2) is not adequately instructed on the limits of penalty assessments imposed by the applicable principles of deterrence and punishment;

(3) is not expressly prohibited from awarding penalty assessments, or determining the amount of an award of penalty assessments, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Sandoz;

(4) is permitted to award penalty assessments under a standard for determining liability for penalty assessments that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes penalty assessments permissible;

(5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for penalty assessments; and

(6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Sandoz's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law, and public policies of the State of Iowa.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

27. To the extent penalty assessments are sought, Plaintiff's claims for penalty assessments against Sandoz cannot be sustained because an award of penalty assessments that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of penalty assessments that may be imposed, would:

(1) violate Sandoz's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution;

(2) violate Sandoz's right not to be subjected to an excessive award; and

(3) be improper under the Constitution, common law, and public policies of the State of Iowa.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

28. Some or all of Plaintiff's claims against Sandoz arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to properly establish appropriate reimbursement rates.

TWENTY-NINTH AFFIRMATIVE DEFENSE

29. The State's claims against Sandoz are barred, in whole or in part, by the existence and terms of the written rebate agreement between Sandoz and the Secretary of the Department of Health and Human Services ("HHS") on behalf of HHS and all States, entitled, "Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement."

THIRTIETH AFFIRMATIVE DEFENSE

30. Plaintiff's claims against Sandoz are misjoined with Plaintiff's claims against other Defendants and must be severed.

THIRTY-FIRST AFFIRMATIVE DEFENSE

31. Plaintiff's claims are barred, in whole or in part, by the Noerr Pennington doctrine to the extent such claims are premised, in whole or in part, on alleged statements or conduct by Sandoz in judicial, legislative or administrative proceedings of any kind or at any level of government.

THIRTY-SECOND AFFIRMATIVE DEFENSE

32. Plaintiff failed to state with particularity and failed to plead with particularity the fraud-based allegations in the Complaint as required by FRCP 9(b).

THIRTY-THIRD AFFIRMATIVE DEFENSE

33. Plaintiff's claims against Sandoz are barred, in whole or in part, because Sandoz did not knowingly cause to be presented to an officer or employee of the State a false or fraudulent claim for payment or statement nor conspired to defraud the State by getting a false or fraudulent claim allowed or paid, as required under Iowa Social Service Law § 366-b.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

34. The claims alleged herein, based on the facts alleged, are barred by Plaintiff's own negligence or gross negligence.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

35. Plaintiff fails to allege facts or a cause of action against Sandoz sufficient to support a claim for prejudgment interest or any other relief.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

36. The State's claims are barred, in whole or in part, because they violate the Iowa Constitution, insofar as the State seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

37. The State fails to state with particularity facts to support claims of fraudulent conduct against Sandoz contained in the Complaint, in violation of Rule 9 of the Federal Rules of Civil Procedure.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

38. Sandoz has not knowingly made or caused to be made any false statement or representation of a material fact, as required to sustain a claim under Iowa Social Services Law § 145-b.

THIRTY-NINTH AFFIRMATIVE DEFENSE

39. Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a consumer within the meaning of the Iowa Consumer Fraud Act.

FORTIETH AFFIRMATIVE DEFENSE

40. Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a person within the meaning of the Iowa Consumer Fraud Act.

FORTY-FIRST AFFIRMATIVE DEFENSE

41. Some or all of Plaintiff's claims against Sandoz arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligations.

FORTY-SECOND AFFIRMATIVE DEFENSE

42. Plaintiff's claims against Sandoz are barred because Plaintiff and/or its agents knew and were aware that AWP was not an actual average of wholesale prices or the actual acquisition cost of pharmaceuticals. Legal and equitable principles preclude this action for damages and injunctive relief.

FORTY-THIRD AFFIRMATIVE DEFENSE

43. Plaintiff's prayers for relief in the form of restitution are barred, in whole or in part, because Sandoz did not retain any money belonging to Plaintiff as a result of any alleged overpayments.

FORTY-FOURTH AFFIRMATIVE DEFENSE

44. Plaintiff's claims against Sandoz are barred in whole or in part by the voluntary payment doctrine.

FORTY-FIFTH AFFIRMATIVE DEFENSE

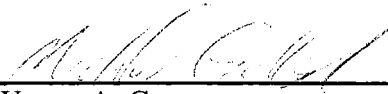
45. Sandoz hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, Sandoz prays that this Court:

1. Dismiss the Complaint with prejudice and enter judgment in favor of Sandoz and against Plaintiff;
2. Award Sandoz its costs and expenses; and
3. Grant such other and further relief for Sandoz as this Court deems just and proper.

Respectfully submitted,

Dated: September 18, 2008



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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the ANSWER AND AFFIRMATIVE DEFENSES OF SANDOZ INC. TO THE STATE OF IOWA'S COMPLAINT was delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on September 18, 2008, for posting and notification to all parties.

September 18, 2008

/s/ Lara Berwanger
Lara Berwanger